The abstract of the disclosure is objected to because the abstract has not been presented in the proper domestic form. Correction is required. See MPEP § 608.01(b).

Claim 3 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend on other claims in the alternative only. See MPEP § 608.01(n).

Claim 2 is objected to because of the following informalities: a period is missing at the end of claim 2. Appropriate correction is required.

Claims 1 and 4-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutically acceptable addition salts, does not reasonably provide enablement for solvates, enantiomers, diastereomers, polymorphs and metabolites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompass any solvates, enantiomers, diastereomers, polymorphs and metabolites of the claimed compounds.

(B) The amount of direction provided by the inventor.

The inventor has not provided any examples of specific solvates, enantiomers, diastereomers, polymorphs or metabolites nor any directions of how to prepare the same.

(C) The existence of working examples.

No working examples of solvates enantiomers, diastereomers, polymorphs or metabolites have been set forth in the specification.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori of which specific solvates, enantiomers, diastereomers, polymorphs or metabolites will have a desired antibacterial activity, it would take an enormous amount of trial and error to prepare various solvates, enantiomers, diastereomers, polymorphs and metabolites and to test the same for their effectiveness as antibacterial agents.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacterial infections, does not reasonably provide enablement for a method of preventing bacterial infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

(A) The breadth of the claims.

The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. There is no evidence that entry could be prevented.

(B) The state of the prior art.

The prevention of bacterial infections with erythromycin derivatives is not known in the prior art.

(C) The amount of direction provided by the inventor.

The inventor has not stated whether the prevention if effective for days, months, years or whether permanent prevention is achieved.

(D) The existence of working examples.

No working examples directed to prevention of bacterial infections have been provided by the applicant.

(E) the quantity of experimentation needed to use the invention based on the content of the disclosure.

Because there is no way to predict a priori if the claimed compounds are effective in preventing bacterial infections, it would take an enormous amount of trial and error to test various compounds encompassed by the present for their effectiveness in preventing various bacterial infections.

Claims 8-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in Formula I (claims 8, 18, 28 and 38) for variables R3, R', R", R3, Y, Z, U, and V. Claim 8 is further indefinite in that two definations of the variable R" have been set forth in sad claim. Further, the process claims 8-47 are

indefinite in that the claims are directed to desmethylating the compound, while Formula I encompasses a compound wherein R2 is methyl.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Asaka et al (U.S. Patent No. 6,140,479).

Asaka et al disclose the claimed compounds wherein R2 and R3 are methyl groups having antibacterial activity (columns 1-2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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